

Briefing Paper
Biotech MCAN J-15-0008, 0009, 0010, 0011, 0012

PART I: BACKGROUND DATA

Program Manager: Jesse Miller

Technical Integrator: Gwen McClung

Review Team: Mark Segal, Alie Muneer, Joe Avcin, David Lynch, Ron Ward, Gwen McClung

Dispo Meeting Date: June 8, 2015

A. CBI Claims: Chemical identity, Recipient microorganism, Donor microorganism, Genetic construct, Exposure, Production volume, Process information.

B. Submitter: Taurus Energy AB

C. Chemical Identity:

[REDACTED]

Recipient Microorganism:

Donor microorganism:

[REDACTED]

D. Production volume

[REDACTED]

E. Use: Fuel ethanol production.

PART II: Introduction

The Agency has received a Microbial Commercial Activity Notice from Taurus Energy AB for five intergeneric strains of *S. cerevisiae* for ethanol production from glucose, galactose, mannose, fructose, or xylose in anaerobic fermentations of lignocellulosic feedstocks. These strains were given the following designations:

[REDACTED] respectively given MCAN designations J-15-08, J-15-09, J-15-10, J-15-11, and J-15-12. The initial intent was to introduce the [REDACTED]

[REDACTED].
Following transformation with several DNA Constructs, a resulting strain was further improved by crossing it back to its parent strain [REDACTED]. Then the strain was subjected to directed evolution by growth on a defined xylose medium. It was then found that the resulting submission strains, which were individual colonies selected off of agar plates, no longer contained the *S. stipitis xyl2* gene. [REDACTED]

[REDACTED] The final strains appear to have identical intergeneric components and differ because of mutations occurring during directed evolution.

Although *S. cerevisiae* is one of the ten microorganisms eligible for the 5(h)4 Tiered Exemptions from MCAN reporting, the company has chosen to submit this strain for an MCAN review because it is intended for use in, and thus transport to, multiple ethanol production facilities in the U.S. The transport of the microorganism to various facilities is outside the realm of the Tier I Exemption and each ethanol production facility would need to separately qualify for the Tier I Exemption. Therefore, the company is submitting this single MCAN for a thorough review of the intergeneric microorganisms given their intended use at a number of different ethanol plants.

PART III: Recommendation and Rationale

Drop from further review.

There is low risk to human health and the environment associated with the production of the five intergeneric strains of [REDACTED]. The genetic modifications do not pose concerns. The only intergeneric sequences are the [REDACTED]

[REDACTED] The submission microorganisms pose low risk.

PART IV: Risk Summary

A. Human Health Hazard

The potential health hazards of the submission microorganisms, *Saccharomyces cerevisiae*, have been evaluated by Ward (2015). The recipient species *S. cerevisiae* is a yeast commonly used in food and beverage production and was found to pose low human health risk assessment in the 5(h)(4) Tiered Exemptions.

The submission microorganisms and the introduced genetic material do not pose pathogenicity or toxicity concerns. There is a low concern for potential allergy from exposure to the submission microorganism. There is no concern for the use of antibiotic resistance genes since the antibiotic selection marker used during construction of the submission microorganism were removed from the final constructs.

B. Ecological Hazards

The ecological hazards of the submission microorganisms have been evaluated by Muneer (2015). [REDACTED]

The production strain may be expected to survive in the environment if inadvertently released from ethanol production facilities, however, its potential survival does not pose concerns. Also, releases of the microorganism from closed system manufacture and use in ethanol facilities are expected to be low.